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References Cited

OTHER PUBLICATIONS

- USPTO U.S. Appl. No. 14/099,623_Mar. 5, 2014_Restriction_Requirement.
- USPTO U.S. Appl. No. 14/099,623_Jul. 18, 2014_Non-Final_Office_Action.
- USPTO U.S. Appl. No. 14/099,623_Dec. 15, 2014_Notice_of_Allowance.
- USPTO U.S. Appl. No. 14/106,655_Jul. 3, 2014_Restriction_Requirement.
- USPTO U.S. Appl. No. 14/106,655_Dec. 8, 2014_Non-Final_Office_Action.
- USPTO U.S. Appl. No. 14/125,554_Dec. 5, 2014_Restriction_Requirement.
- USPTO U.S. Appl. No. 14/125,554_Apr. 14, 2015_Non-Final_Office_Action.
- USPTO U.S. Appl. No. 14/136,048_Nov. 4, 2014_Restriction_Requirement.
- USPTO U.S. Appl. No. 14/136,048_Mar. 12, 2015_Non-Final_Office_Action.
- USPTO U.S. Appl. No. 14/475,814_Oct. 1, 2014_Non-Final_Office_Action.
- USPTO U.S. Appl. No. 14/475,814_Feb. 13, 2015_Notice_of_Allowance.
- USPTO U.S. Appl. No. 14/475,864_Oct. 2, 2014_Non-Final_Office_Action.
- USPTO U.S. Appl. No. 14/475,864_Feb. 11, 2015_Notice_of_Allowance.
- USPTO U.S. Appl. No. 14/476,040_Mar. 26, 2015_Restriction_Requirement.
- USPTO U.S. Appl. No. 14/521,230_Dec. 5, 2014_Restriction_Requirement.
- USPTO U.S. Appl. No. 14/521,230_Feb. 18, 2015_Non-Final_Office_Action.
- USPTO U.S. Appl. No. 14/624,051_Apr. 7, 2015_Non-Final_Office_Action.
- Utian, Wulf H, et al., Relief of vasomotor symptoms and vaginal atrophy with lower doses of conjugated equine estrogens, *Fertility and Sterility*, vol. 75(6) pp. 1065, Jun. 2001.
- Voegtline et al., Dispatches from the interface of salivary bioscience and neonatal research, *Frontiers in Endocrinology*, Mar. 2014, vol. 5, article 25, 8 pages.
- Waddell et al., Distribution and metabolism of topically applied progesterone in a rat model, *Journal of Steroid Biochemistry & Molecular Biology* 80 (2002) 449-455.
- Waddell et al., The Metabolic Clearance of Progesterone in the Pregnant Rat: Absence of a Physiological Role for the Lung, *Biology of Reproduction* 40, 1188-1193 (1989).
- Walter et al., The role of progesterone in endometrial angiogenesis in pregnant and ovariectomised mice, *Reproduction* (2005) 129 765-777.
- Weber, E.J., Corn Lipids, *Cereal Chem.*, vol. 55(5), pp. 572-584, The American Assoc of Cereal Chem, Sep.-Oct. 1978.
- Weber, M.T., et al., Cognition and mood in perimenopause: A systematic review and meta-analysis, *J. Steroid Biochem. Mol. Biol.* (2013), Elsevier.
- Weintraub, Arlene, "Women fooled by untested hormones from compounding pharmacies," *Forbes*, Feb. 20, 2015; retrieved online at <http://onforb.es/1LIUm1V> on Feb. 23, 2015, 3 pages.
- Whitehead et al., Absorption and metabolism of oral progesterone, *The British Medical Journal*, vol. 280, No. 6217 (Mar. 22, 1980), pp. 825-827, BMJ Publishing Group.
- Wiranidchapon, Chutima, Method of preparation does not affect the miscibility between steroid hormone and polymethacrylate, *Thermochimica Acta* 485, Elsevier, pp. 57, 2009.
- Wood et al., Effects of estradiol with micronized progesterone or medroxyprogesterone acetate on risk markers for breast cancer in postmenopausal monkeys, *Breast Cancer Res Treat* (2007) 101:125-134.
- Wren et al., Effect of sequential transdermal progesterone cream on endometrium, bleeding pattern, and plasma progesterone and salivary progesterone levels in postmenopausal women, *Climacteric*, 2000, 3(3), pp. 155-160. <http://dx.doi.org/10.1080/13697130008500109>.
- Wu et al., Gene Expression Profiling of the Effects of Castration and Estrogen Treatment in the Rat Uterus, *Biology of Reproduction* 69, 1308-1317 (2003).
- Yalkowsky, Samuel H, & Valvani, Shri C, Solubility and Partitioning I: Solubility of Nonelectrolytes in Water, *J. of Pharmaceutical Sciences*, vol. 69(8) pp. 912-22, 1980.
- Yalkowsky, Samuel H, *Handbook of Aqueous Solubility Data, Solutions*, 2003, pp. 1110-1111, CRC Press, Boca Raton, London, New York, Wash. D.C.
- Yue, W., Genotoxic metabolites of estradiol in breast: potential mechanism of estradiol induced carcinogenesis, *Journal of Steroid Biochem & Mol Biology*, vol. 86 pp. 477-486, 2003.
- Zava, David T. et al., Percutaneous absorption of progesterone, *Maturitas* 77 (2014) 91-92, Elsevier.
- Zava, David T., *Topical Progesterone Delivery and Levels in Serum, Saliva, Capillary Blood, and Tissues*, Script, ZRT Laboratory, pp. 4-5. http://www.zrtlab.com/component/docman/cat_view/10-publications?itemid.
- Cicinelli et al., "First uterine pass effect" is observed when estradiol is placed in the upper but not lower third of the vagina, *Fertility and Sterility*, vol. 81, No. 5, May 2004, pp. 1414-1416.
- Cicinelli, Intravaginal oestrogen and progestin administration: advantages and disadvantages, *Best Practices & Research Clinical Obstetrics and Gynaecology* vol. 22, No. 2, 2008, pp. 391-405.
- Eugster-Hausmann et al., "Minimized estradiol absorption with ultra-low-dose 10 µg 17β-estradiol vaginal tablets," *Climacteric* 2010;13:219-227.
- Knuth et al., Hydrogel delivery systems for vaginal and oral applications: Formulation and biological considerations, *Advanced Drug Delivery Reviews*, vol. 11, No. 1-2, Jul.-Aug. 1993, pp. 137-167.
- Regidor, P., "Progesterone in Peri- and Postmenopause: A Review," *Geburtshilfe Frauenheilkd*, Nov. 2014, 74(11):995-1002.
- Simon et al., "A vaginal estradiol softgel capsule, TX-004HR, has negligible to verylow systemic absorption of estradiol: Efficacy and pharmacokineticdata review," *Maturitas* 99 (2017) 51-58.
- Stefanick, "Estrogens and progestins: background and history, trends in use, and guidelines and regimens approved by the US Food and Drug Administration," *The American Journal of Medicine* (2005) vol. 118 (12B), 64S-73S.
- USPTO U.S. Appl. No. 12/561,515 Dec. 12, 2011 Non-Final Office Action.
- USPTO U.S. Appl. No. 12/561,515 Oct. 26, 2012 Final Office Action.
- USPTO U.S. Appl. No. 12/561,515 Sep. 11, 2013 Notice of Allowance.

* cited by examiner